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Reynolds American wants FDA to ban vapor e-cigs

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Reynolds American Inc. has fired an expected shot across the bow of small vapor cigarette manufacturers.

A Reynolds division recommended to the Food and Drug Administration in a 119-page submission that the agency ban the use of vapor electronic cigarettes

Traditional e-cigs are battery-powered devices that heat a liquid nicotine solution in a self-contained disposable cartridge and create a vapor that is inhaled. The manufacturers have provided few flavor choices, in part in expectations that the FDA would limit flavorings as they do with combustible cigarettes.

By comparison, vapor products can feature a liquid capsule that is inserted into a cartridge, known as an open-system format. Vapors offer consumers a wider variety of flavors, including fruits and candy.

“We believe FDA should not allow such products to be sold or marketed,” Reynolds spokesman David Howard said in discussing the company’s submission. “We believe open-system vapor products create unique public health risks.

“These systems are highly subject to adulteration and tampering, they are manufactured largely overseas in facilities that would, as proposed, fall outside regulatory inspection and oversight, and many nicotine liquids are sold in non-child-resistant packaging in flavors that may be appealing to youth.”

Industry observers say much of the nicotine liquid for the open-system vapor products are made in China or in unregulated vape shops, a sizable number of which are operating in the Triad.

Altria Group Inc. and Lorillard Inc also submitted recommendations – both less stringent than Reynolds – during a public comment period that expired in August.

The FDA began regulating tobacco products and marketing in June 2009, but it does not have the authority to ban nicotine or tobacco.

The industry, advocacy groups, analysts and adult smokers have been waiting years for the FDA to decide on approving e-cigs and vapors as a smoking-cessation device. A Wild Wild West environment has emerged in the absence of FDA e-cig regulations.

Reynolds’ recommendations did not come as a surprise to vapor e-cig supporters who have expressed concern since the category’s emergence about federal regulators allowing the Big Three to dominate e-cigs as they have combustible cigarettes and moist snuff.

“R.J. Reynolds’ call for the FDA to ban the majority of e-cigarette products should be seen for what it really is — an admission that it simply cannot compete in the current e-cigarette market,” said Gregory Conley, president of the American Vaping Association.

“Recent market reports show that while sales of open-system e-cigarette products and e-liquid are booming, sales of closed-system cigarette lookalikes – the kind that Reynolds sells – have stagnated.”

The stakes over the e-cig vs. vapor debate could be significant financially, as the industry changes.

Wells Fargo Securities analyst Bonnie Herzog estimated overall U.S. e-cig revenue reached \$2 billion in 2013. She projects it will increase up to \$10 billion by 2017.

Herzog predicts Reynolds will have \$4 billion in revenue from e-cigs in 2021, compared with \$3.9 billion from conventional cigarettes. That's compared with barely any e-cig revenue and \$6.4 billion in conventional cigarette revenue for 2013.

Herzog also has noted a significant pickup in vapor sales in recent months.

The World Health Organization said in an Aug. 26 report there are 466 global e-brands and that \$3 billion was spent globally on the products in 2013. "Sales are forecasted to increase by a factor of 17 by 2030," the report said.

The WHO report's authors expressed concern about the ability to manipulate the vapor products to insert liquid compounds other than nicotine solutions. They said there has not been near enough time to determine whether e-cigs will contribute to "many diseases of interest, such as cancer. ... The association of e-cigs with such diseases will not be available for years or even decades."

Reynolds recently began a national launch of its e-cig brand, Vuse, that top executive Susan Cameron has touted as a "game changer" for the sector.

Reynolds is confident enough in Vuse that it plans to sell the top-selling U.S. brand, blu eCigs, as part of a \$27.4 billion offer for Lorillard. Reynolds would sell blu eCigs and its 41 percent U.S. market share to Imperial Tobacco Group Plc in a related \$7.1 billion deal.

Cameron said during an investor presentation last week that adult smokers are experimenting with self-contained e-cigs and open system vapor products.

“I think that what you’ve seen is as consumers have tried a lot of these e-cigare that aren’t satisfying, this has driven a lot of the growth of what we call tanks,” Cameron said.

“The growth of those is driven by the consumer’s desire to get satisfaction. If you’re not getting satisfaction out of the e-cigarette format because you’re not getting the nicotine that you want, then if you go to those tanks, you can figure how much nicotine you want, right. You fill it yourself.

“Our position is really that these open tanks are really not appropriate. And the reason for that is because people can put whatever they want to in those tanks, this is a lot of the public outcry. People are putting a lot of things other than nicotine into these pipes.”

For example, there are companies making e-mail pitches for selling e-liquids containing cannabis.

“Second of all, if you really load a lot of nicotine into a pipe, and there is nothing to stop a kid from picking it up, this is not good,” Cameron said. “So we believe that closed systems are the way that regulators should evolve.”

Reynolds said that if the FDA does allow open-system vapor products to be sold “should create a level playing field on which all manufacturers of non-combustible deemed product categories are subject to equal treatment.”

“Such equal treatment will ensure that all such products meet the health and safety requirements that FDA determines are necessary to safeguard and promote the public health.”

Lorillard said in its 132-page submission that e-cigs “hold the potential to advance the public health dramatically by moving existing users of conventional tobacco products to lower risk options.”

“In fact, an international expert panel recently estimated that electronic cigarette

have only 4 percent of the maximum relative harm of conventional cigarettes, suggesting that substitution of electronic cigarettes for conventional cigarette: likely to provide a significant public health benefit.”

“Lorillard recognizes that reasonable regulation can help foster product quality and consistency, as well as responsible marketing to ensure that the public health benefits of this product category are fulfilled.”

Conley cited surveys of e-cig users that said smokers who try vapor products “a far more likely to be smoke-free than are those who use closed system products that are designed to resemble and taste like cigarettes.”

“We also encourage the Federal Trade Commission to consider Reynolds’ eager to see its competitors banned in deciding whether to approve a proposed merger between Reynolds and Lorillard.”

Scott Ballin, past chairman of the Coalition on Smoking or Health, said he expects the FDA to place severe restriction on the open-system vapor products for the reasons Cameron and Reynolds cited.

“The lack of regulatory oversight over the vapor liquid tanks may back the FDA into that stance since otherwise, you open a whole can of worms on what can go into those tanks,” Ballin said.

“The FDA also needs to step in to say that not all e-cigs are OK, and not all of them should be on the market.”

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